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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/774,550 | 02/09/2004 | Andrew F. Hall | 5236-000476/US | 8958 |
| 7590 | 11/03/2006 | | EXAMINER | |
| Bryan K. Wheelock Harness, Dickey & Pierce, P.L.C. Suite 400 7700 Bonhomme St. Louis, MO 63105 | | | PEFFLEY, MICHAEL F | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3739 | |
| DATE MAILED: 11/03/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/774,550 | HALL ET AL. | |
| | Examiner | Art Unit | |
| | Michael Peffley | 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 September 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8, 12-20 and 26-38 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 19, 20 and 26-28 is/are allowed.
- 6) Claim(s) 1-8, 12-18 and 29-38 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received September 5, 2006, have been fully considered by the examiner. The following is a complete response to the September 5, 2006 communication.

Claim Objections

Claim 33 is objected to because of the following informalities: claim 33 lacks proper antecedent basis for "the core element" (line 6). Appropriate correction is required. Applicant failed to address this issue in the September 5, 2006 communication.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims depend from canceled claim 21 making the scope of the claims unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Bourne et al (5,911,720).

Bourne et al disclose a catheter device having a sheath (124) a sleeve (115) slidably mounted in the sheath and capable of telescoping from the sheath, an extension member (116) having proximal and distal ends slidably mounted within the sleeve. As seen in Figure 11, the distal end portion of the extension member is more flexible than the distal end of the sleeve. As addressed throughout the disclosure, the device includes multiple electrodes at the distal end of the extension members and uses multiple magnets (42,44) which are capable of being oriented by application of an externally applied magnetic field. With regard to the amendments made to claim 1, the electrode (30) is provided at the distal end of the extension member and connected to a source of energy, and the electrode/magnet (30) is relatively rigid with a portion of the extension member (36 or 38) proximal to the magnet being flexible such that the catheter bends at a point proximal to the distal end portion having the magnet (30).

Claims 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Fleischman et al (5,545,193).

As seen in Figure 51, Fleischman et al disclose a telescoping device comprising an outer sheath (178) and an inner core (224-226) slidably disposed within the sheath. The distal end of the inner core member may be oriented independently of the outer

sheath. The Fleischman et al disclosure fully addresses the steerable nature of the device and its method of use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-18 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al (6,292,678) in view of the teaching of Fleischman et al ('193).

Hall et al disclose a magnetically navigable catheter having a tubular magnetic member (36) and a plurality of electrodes (38) thereon. The magnetic member defines a passage in view of its tubular shape. Hall et al also disclose the use of plurality annular magnets (Figures 11-16). However, the Hall et al electrodes are disclosed as being pads on the surface of the device, and not annular electrodes that would provide a passage as now recited in claim 12.

Fleischman et al disclose an analogous steerable catheter for the treatment of tissue with RF energy. In particular, Fleischman et al teach that it is known to provide such a catheter with a variety of types of electrodes for treating tissue, including annular electrodes such that the device could treat tissue on either side of the catheter and electrode pads (202 – Figures 42 and 45) to allow treatment with only one portion of the catheter.

To have provided the Hall et al device with annular electrodes to allow for treatment of tissue on any side of the device would have been an obvious modification for one of ordinary skill in the art in view of the teaching Fleischman et al. Such an annular electrode would inherently provide a passage through which a fluid could be passed.

Allowable Subject Matter

Claims 19, 20 and 26-28 are allowed.

Claims 29-31 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed September 5, 2006 have been fully considered but they are not persuasive.

Regarding the rejection of claims 1-8, the examiner maintains that the Bourne et al reference clearly provides a proximally located flexible section as discussed in the body of the rejection. Applicant's assertion that Bourne et al fail to provide such a flexible section is deemed to be without merit in view of the rejection above.

Regarding the rejection of claims 12-18, applicant asserts that the Hall et al reference fails to disclose a fluid lumen through the embodiments shown in Figures 2A-2C and 3A-3C. It is the applicant's position that the "tether" could not provide a fluid flow and fluid is therefore not provided to the magnetic tubular members (36,56). The

examiner disagrees. Hall et al disclose at numerous portions of the specification that fluid is provided through the tethers in all embodiments. Column 6, lines 29-39 specifically address the embodiment of Figure 2C and state that the treatment element could be a cryogenic contact, which contact would require a fluid flow through the tether to provide a cryogen to the contacts on the contact portion. Lines 37-39 also expressly state that fluid opening may be provided to inject fluid, which fluid would necessarily need to be provided through the tether members. Column 9, lines 15-28 further expressly state that fluid is provided through the tether members such that fluid may be provided to the magnetic members on the distal end. It is the examiner's position that applicant's arguments are without merit and that Hall et al clearly provides a fluid as set forth in the claims. The examiner maintains the rejection of claims 12-18 as being tenable. Further, newly added claims 35-38 recite no additional features which would distinguish over the prior art. The electrodes of the prior art are clearly configured to create a "focal lesion" and have lead wires which are "configured to be connected to a measuring device". The Hall magnetic member is clearly rigid relative to the "tether" portion, and the electrodes are made of a radio-opaque metal viewable under fluoroscopic procedures.

Finally, it is noted that applicant failed to address the 35 USC 102 rejection of claims 32-34 as being anticipated by Fleischman et al ('193). This rejection is maintained and made final.

Conclusion

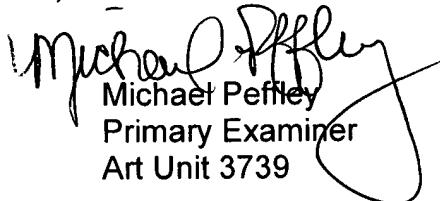
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Michael Pefley
Primary Examiner
Art Unit 3739

mp
October 30, 2006